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Attorney Docket No.

0430
3-19-02

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Date: 03/15/02By: Meredith A. Ahern

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: FIRLIK ET AL.

APPLICATION NO.: 10/072,700

FILED: February 7, 2002

FOR: METHODS AND APPARATUS FOR
EFFECTUATING A CHANGE IN A
NEURAL-FUNCTION OF A PATIENT

ART UNIT: UNKNOWN

CONFIRMATION NO.: UNKNOWN

L. Park
5-7-02
3767 #2/3-D.5.Information Disclosure Statement Within Three Months of
Application Filing or Before First Action – 37 CFR 1.97(b)

Assistant Commissioner for Patents
Washington, D.C. 20231

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Sir:

1. Timing of Submission

This information disclosure is being filed within three months of the filing date of this application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever occurs last [37 CFR 1.97(b)]. The references and related application listed on the enclosed Form PTO/SB/08A (modified) may be material to the examination of this application; the Examiner is requested to make them of record in the application.

2. Cited Information

- Copies of the following references and related application are enclosed:
- All cited references
- References marked by asterisks
- The following:
- Copies of the following references can be found in parent application Ser. No. _____
- All cited references
- References marked by asterisks
- The following:
- The following references are not in English. For each such reference, the undersigned has enclosed (i) a translation of the reference; (ii) a copy of a

communication from a foreign patent office or International Searching Authority citing the reference, (iii) a copy of a reference which appears to be an English-language counterpart, or (iv) an English-language abstract for the reference prepared by a third party. Applicant has not verified that the translation, English-language counterpart or third-party abstract is an accurate representation of the teachings of the non-English reference, though, and reserves the right to demonstrate otherwise.

- All cited references
- References marked by ampersands
- The following:

3. Effect of Information Disclosure Statement (37 CFR 1.97(h))

This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

4. Fee Payment

No fees are believed due. However, should the Commissioner determine that fees are due in order for this Information Disclosure Statement to be considered, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-0665.

5. Patent Term Adjustment (37 CFR 1.704(d))

- The undersigned states that each item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this statement. 37 C.F.R. § 1.704(d).

Respectfully submitted,



Paul T. Parker
Registration No. 38,264

Date: March 15, 2002

Correspondence Address:

Perkins Coie LLP
Customer No. 25096
Phone: (206) 583-8888

COMPLETE IF KNOWN

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

MAR 21 2002

U.S. PATENT & TRADEMARK OFFICE

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|----------------------|------------------|
| Application Number | 10/072,700 |
| Confirmation Number | Unknown |
| Filing Date | 02/07/02 |
| First Named Inventor | Andrew D. Firlik |
| Group Art Unit | Unknown |
| Examiner Name | Unknown |

Sheet

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of

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Attorney Docket No.

337348020US4

U.S. PATENT DOCUMENTS

| EXAMINER INITIALS | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|-------------------|-----------|----------------------|----------------------|---|---------------------------------------|---|
| | | NUMBER | Kind Code (if known) | | | |
| AA | 5,713,922 | | | King | 02/03/98 | |
| AB | 5,215,086 | | | Terry, Jr. et al. | 06/01/93 | |
| AC | 5,716,377 | | | Rise et al. | 02/10/98 | |
| AD | 5,975,085 | | | Rise | 11/02/99 | |
| AE | 6,066,163 | | | John | 05/23/00 | |
| AF | 3,650,276 | | | Burghelle et al | 03/21/72 | |
| AG | 4,140,133 | | | Kastrubin et al. | 02/20/79 | |
| AH | 4,542,752 | | | DeHaan et al. | 09/24/85 | |
| AI | 4,607,639 | | | Tanagho et al. | 08/26/86 | |
| AJ | 4,646,744 | | | Capel | 03/03/87 | |
| AK | 4,844,075 | | | Liss et al. | 07/04/89 | TC 3753 APR 1 1994 REC'D |
| AL | 4,865,048 | | | Eckerson | 09/12/89 | |
| AM | 5,002,053 | | | Garcia-Rill et al. | 03/26/91 | |
| AN | 5,031,618 | | | Mullett | 07/16/91 | |
| AO | 5,092,835 | | | Schurig et al. | 03/03/92 | |
| AP | 5,143,089 | | | Alt | 09/01/92 | |
| AQ | 5,169,384 | | | Bosniak et al. | 12/08/92 | |
| AR | 5,304,206 | | | Baker, Jr. et al. | 04/19/84 | |
| AS | 5,358,513 | | | Powell, III et al. | 10/25/94 | |
| AT | 5,370,672 | | | Fowler et al. | 12/06/94 | |
| AU | 5,417,719 | | | Hull et al. | 05/23/95 | |
| AV | 5,537,512 | | | Hsia et al. | 07/16/96 | |
| AW | 5,540,736 | | | Haimovish et al. | 07/30/96 | |
| AX | 5,411,540 | | | Edell et al. | 05/02/95 | |
| AY | 5,549,655 | | | Erickson | 08/27/96 | |
| AZ | 5,885,976 | | | Sandyk | 03/23/99 | |
| BA | 5,886,769 | | | Zolten | 03/23/99 | |
| BB | 5,904,916 | | | Hirsch | 05/18/99 | |
| BC | 5,938,688 | | | Schiff | 08/17/99 | |

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|---|----|-----------|-----------------------|--------------------------|--|
| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | COMPLETE IF KNOWN | |
| | | | | Application Number | 10/072,700 |
| | | | | Confirmation Number | Unknown |
| | | | | Filing Date | 02/07/02 |
| | | | | First Named Inventor | Andrew D. Firlik |
| | | | | Group Art Unit | Unknown |
| | | | | Examiner Name | Unknown |
| Sheet | | 2 | of | Attorney Docket No. | |
| | | | | 337348020US4 | |
| | BD | 5,591,216 | Testerman et al. | 01/07/97 | |
| | BE | 5,593,432 | Crowther et al. | 01/14/97 | |
| | BF | 5,628,317 | Starkebaum et al. | 05/13/97 | |
| | BG | 5,683,422 | Rise | 11/04/97 | |
| | BH | 5,702,429 | King | 12/30/97 | |
| | BI | 5,711,316 | Elsberry et al. | 01/27/98 | |
| | BJ | 5,713,923 | Ward et al. | 02/03/98 | |
| | BK | 5,735,814 | Elsberry et al. | 04/07/98 | |
| | BL | 5,752,979 | Benabid | 05/19/98 | |
| | BM | 5,782,798 | Rise | 07/21/98 | |
| | BN | 5,792,186 | Rise | 08/11/98 | |
| | BO | 5,797,970 | Pouvreau | 08/25/98 | RECEIVED U.S. PATENT & TRADEMARK OFFICE |
| | BP | 5,814,014 | Elsberry et al. | 09/29/98 | RECEIVED U.S. PATENT & TRADEMARK OFFICE |
| | BQ | 5,814,092 | King | 09/29/98 | RECEIVED U.S. PATENT & TRADEMARK OFFICE |
| | BR | 5,824,021 | Rise | 10/20/98 | RECEIVED U.S. PATENT & TRADEMARK OFFICE |
| | BS | 5,832,932 | Elsberry et al. | 11/10/98 | RECEIVED U.S. PATENT & TRADEMARK OFFICE |
| | BT | 5,833,709 | Rise et al. | 11/10/98 | RECEIVED U.S. PATENT & TRADEMARK OFFICE |
| | BU | 5,843,148 | Gijsbers et al. | 12/01/98 | |
| | BV | 5,843,150 | Dreessen et al. | 12/01/98 | |
| | BW | 5,893,883 | Torgerson et al. | 04/13/99 | |
| | BX | 5,913,882 | King | 06/22/99 | |
| | BY | 5,925,070 | King et al. | 07/20/99 | |
| | BZ | 5,941,906 | Barreras, St. et al. | 08/24/99 | |
| | CA | 5,964,794 | Bolz et al. | 10/12/99 | |
| | CB | 5,978,702 | Ward et al. | 11/02/99 | |
| | CC | 6,011,996 | Gielen et al. | 01/04/00 | |
| | CD | 6,018,682 | Rise | 01/25/00 | |
| | CE | 6,021,352 | Christopherson et al. | 02/01/00 | |
| | CF | 6,026,326 | Bardy | 02/15/00 | |
| | CG | 6,042,579 | Elsberry et al. | 03/28/00 | |
| | CI | 6,057,847 | Sever, Jr. | 05/02/00 | |

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

MAR 21 2002

PATENT & TRADEMARK OFFICE
U.S. DEPARTMENT OF COMMERCE**COMPLETE IF KNOWN**

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|----------------------|------------------|
| Application Number | 10/072,700 |
| Confirmation Number | Unknown |
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| First Named Inventor | Andrew D. Firlik |
| Group Art Unit | Unknown |
| Examiner Name | Unknown |

Sheet 3 of Attorney Docket No. 337348020US4

| | | | | |
|----|------------|-------------------|----------|---|
| CJ | 6,058,331 | King | 05/02/00 | |
| CK | 6,055,456 | Gerber | 04/25/00 | |
| CL | 6,060,048 | Cherksey | 05/09/00 | |
| CM | 6,104,956 | Naritoku et al. | 08/15/00 | |
| CN | 6,104,960 | Duysens et al. | 08/15/00 | |
| CO | 6,122,548 | Starkebaum et al. | 09/19/00 | TO SAC MAIL ROOM |
| CP | 6,126,657 | Edwards et al. | 10/03/00 | MR 1 RECEIVED U.S. PATENT & TRADEMARK OFFICE |
| CQ | 6,128,537 | Rise | 10/03/00 | |
| CR | 6,152,143 | Edwards | 11/28/00 | |
| CS | 6,161,044 | Silverstone | 12/12/00 | |
| CT | 09/802,808 | Firlik | 03/08/01 | |
| CU | 60/325,872 | Sheffield | 09/28/01 | |
| CV | 60/325,978 | Gliner | 09/28/01 | |
| CW | 09/978,134 | Gliner | 10/15/01 | |
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FOREIGN PATENT DOCUMENTS

| *EXAMINER INITIALS* | Cite No. | Foreign Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T |
|---------------------|----------|-------------------------|-----------------------------------|---|---------------------------------------|---|---|
| | | Office | Kind Code Number (if known) | | | | |
| CX | PCT | WO 98/06342 | | Neotonus, Inc. | 02/19/98 | | |
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OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

| *EXAMINER INITIALS* | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume/issue number(s), publisher, city and/or country where published. | T |
|---------------------|----------|---|---|
| CY | | SIEBNER et al., "Lasting cortical activation after repetitive TMS of the motor cortex," NEUROLOGY 54, pp. 956-963 (February 2000) | |
| CZ | | ZIEMANN et al., "Modulation of Plasticity in Human Motor Cortex after Forearm Ischemic Nerve Block," The Journal of Neuroscience, Vol. 18, No. 3, pp. 1115-1123 (February 1998) | |

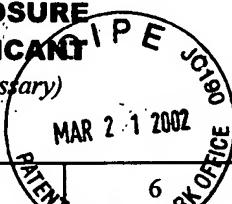
| | | | COMPLETE IF KNOWN | |
|-------|--|--|-----------------------------|------------------|
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| | | | Confirmation Number | Unknown |
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| | | | Group Art Unit | Unknown |
| | | | Examiner Name | Unknown |
| | | | Attorney Docket No. | 337348020US4 |
| Sheet | | 4 | of | 6 |
| DA | | OLIVERI et al., "Paired transcranial magnetic stimulation protocols reveal a pattern of inhibition and facilitation in the human parietal cortex," The Journal of Physiology, 529.2, pp. 461-468 (2000) | | |
| DB | | CLASSEN, et al., "Rapid Plasticity of Human Cortical Movement Representation Induced by Practice," The Journal of Neurophysiology, Vol. 79, No. 2, pp. 1117-1123 (February 1998) | | |
| DC | | LEVY et al., "Functional MRI Evidence of Cortical Reorganization in Upper-Limb Stroke Hemiplegia Treated with Constraint-Induced Movement Therapy," American Journal of Physical Medicine & Rehabilitation, Vol. 80, No. 1, pp. 4-7 (2001) | | |
| DD | | GORDON et al., "Parameters for direct cortical electrical stimulation in the human: histopathologic confirmation," Electroencephalography and clinical Neurophysiology, Vol. 75, pp. 371-377 (1990) | | |
| DE | | CRAMER, S.C. and BASTINGS, E.P., "Mapping clinically relevant plasticity after stroke," Neuropharmacology Vol. 19, No. 5, pp. 842-851 (April 2000) | | |
| DF | | HODGE, JR., C.J. and BOAKYE, M., "Biological Plasticity: The Future of Science in Neurosurgery," Neurosurgery, Vol. 48, No. 1 (January 2001) | | |
| DG | | NITSCHE, M.A. and PAULUS, W., "Excitability changes induced in the human motor cortex by weak transcranial direct current stimulation," The Journal of Physiology, Vol. 527.3, pp. 663-639 (2000) | | |
| DH | | ROSSI et al., "Effects of Repetitive Transcranial Magnetic Stimulation on Movement-related Cortical Activity in Humans," Cerebral Cortex, Vol. 10, No. 8, pp. 802-808 (August 2000) | | |
| DI | | CINCOTTA et al., "Reorganization of the motor cortex in a patient with congenital hemiparesis and mirror movements," Neurology, Vol. 55, pp. 129-131 (2000) | | |
| DJ | | STEFAN et al., "Introduction of plasticity in the human motor cortex by paired associative stimulation," Brain, Vol. 123, No. 3, pp. 575-584 (March 2000) | | |
| DK | | FEYS et al., "Value of somatosensory and motor evoked potentials in predicting arm recovery after a stroke," (October 1999) | | |
| DL | | TURTON, A. and LEMON, R.N., "The contribution of fast corticospinal input to the voluntary activation of proximal muscles in normal subjects and in stroke patients," Exp. Brain Res., Vol. 129, pp. 559-572 (1999) | | |
| DM | | MARTINEZ et al., "Motor hand recovery after stroke Prognostic yield of early transcranial magnetic stimulation," Electromyography. Clin. Neurophysiology, Vol. 39, pp. 405-410 (1999) | | |
| DN | | SAITOU et al., "Cerebral Blood Volume and Oxygenation Among Poststroke Hemiplegic Patients: Effects of 13 Rehabilitation Tasks Measured by Near-Infrared Spectroscopy," Arch. Phys. Med. Rehabil., Vol. 81 pp. 1348-1356 (October 2000) | | |
| DO | | MALENKA, R.C. and NICOLL, R.A., "Long-Term Potentiation – A Decade of Progress?," Neuroscience, Vol. 285, No. 5435, Issue of 17 September 1999, pp. 1870-1874 | | |
| DP | | SANES, J.N. and DONOGHUE, J.P., "Plasticity and Primary Motor Cortex," Annu. Rev. Neurosci. 23:393-415 (2000) | | |

| | | | COMPLETE IF KNOWN | |
|--------------|---|-----------|-----------------------------|------------------|
| | | | Application Number | 10/072,700 |
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| | | | First Named Inventor | Andrew D. Firlik |
| | | | Group Art Unit | Unknown |
| | | | Examiner Name | Unknown |
| Sheet | 5 | of | Attorney Docket No. | 337348020US4 |
| DQ | FRANZINI et al., "Reversal of thalamic hand syndrome by long-term motor cortex stimulation," Journal of Neurosurgery 93:873-875 (2000) | | | |
| DR | WALKER-BATSON et al., "Amphetamine Paired With Physical Therapy Accelerates Motor Recovery After Stroke," Stroke, Vol. 26, No. 12, pp. 2254-2259 (1995) | | | |
| DS | NETZ et al., "Reorganization of motor output in the non-affected hemisphere after stroke," Brain, 120, pp. 1579-1586 (1997) | | | |
| DT | SANES, "The Relation between Human Brain Activity and Hand Movements," NeuroImage 11, pp. 370-374 (2000) | | | |
| DU | SANES, J. and DONOGHUE, J.P., "Plasticity and Primary Motor Cortex," Annual Review of Neuroscience 23:393-415 (2000) | | | |
| DV | SANDKÜHLER, "Learning and memory in pain pathways," Pain 88, pp. 113-118 (2000) | | | |
| DW | DAM et al., "Effects of Fluoxetine and Maprotiline on Functional Recovery in Poststroke Hemiplegic Patients Undergoing Rehabilitation Therapy," Stroke, Vol. 27, No. 7, pp. 1211-1214 (July 1996) | | | |
| DX | BEL, S. and BAUER, B.L., "Dorsal Column Stimulation (DCS): Cost to Benefit Analysis," Acta Neurochirurgica, Suppl. 52, pp. 121-123 (1991) | | | |
| DY | KOPELL et al., "The Continuing Evolution of Psychiatric Neurosurgery," CNS Spectrums, Vol. 5, No. 10, pp. 20-31 (October 2000) | | | |
| DZ | REZAI, "Neurostimulation," Neurological Research, Vol. 22, No. 3 pp. 235-273 (April 2000) | | | |
| EA | TURTON et al., "Contralateral and ipsilateral EMG responses to transcranial magnetic stimulation during recovery of arm and hand function after stroke," Electroencephalography and Clinical Neurophysiology 101 pp. 316-328 (1996) | | | |
| EB | BÜTEFISCH et al., "Mechanisms of use-dependent plasticity in the human motor cortex," Proc. Natl. Acad. Sci. USA, Vol. 97, No. 7, pp. 3661-3665 (March 2000) | | | |
| EC | VAN DER LEE et al., "The Intra- and Interrater Reliability of the Action Research Arm Test: A Practical Test of Upper Extremity Function in Patients With Stroke," Arch. Phys. Med. Rehabil., Vol. 82 pp. 14-19 (January 2001) | | | |
| ED | KAUHANEN et al., "Domains and Determinants of Quality of Life After Stroke Caused by Brain Infarction," Arch. Phys. Med. Rehabil., Vol. 81, pp. 1541-1546 (December 2000) | | | |
| EE | ZIEMANN et al., "Modulation of Plasticity in Human Motor Cortex after Forearm Ischemic Nerve Block," The Journal of Neuroscience 18(3):1115-1123 (February 1998) | | | |
| EF | ROUX et al., "Chronic Motor Cortex Stimulation for Phantom Limb Pain: A Functional Magnetic Resonance Imaging Study: Technical Cast Report," Neurosurgery, Vol. 49, No. 3 (March 2001) | | | |

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)



Sheet

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of

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COMPLETE IF KNOWN

Application Number 10/072,700

Confirmation Number Unknown

Filing Date 02/07/02

First Named Inventor Andrew D. Firlik

Group Art Unit Unknown

Examiner Name Unknown

Attorney Docket No. 337348020US4

| | |
|----|---|
| EG | COHEN et al., "Studies of Neuropathology With Transcranial Magnetic Stimulation," The Journal of Clinical Neurophysiology, Vol. 15, No. 4 (1998) |
| EH | SHIMIZU et al., "Therapeutic efficacy of transcranial magnetic stimulation for hereditary spinocerebellar degeneration," Tohoku Journal of Experimental Medicine, 189(3):203-11 (November 1999) |
| EI | LIEPERT et al., "Treatment-Induced Cortical Reorganization After Stroke in Humans," Stroke, 31:1210-1216 (2000) |
| EJ | SCHIFF et al., "A neuromodulation strategy for rational therapy of complex brain injury states," Neurological Research, Vol. 22 pp. 267-272 (April 2000) |
| EK | GLADSTONE et al., "Enhancing Recovery after Stroke with Noradrenergic Pharmacotherapy: A New Frontier?," Can J. Neurol. Sci., Vol. 27, No. 2 (May 2000) |
| EL | PASCUAL-LEONE et al., "Study and Modulation of Human Cortical Excitability With Transcranial Magnetic Stimulation," Journal of Clinical Neurophysiology, Vol. 15, No. 4 (1998) |
| EM | PASCUAL-LEONE et al., "Transcranial magnetic stimulation and neuroplasticity," Neurophysiology 37, pp. 207-217 (1999) |
| EN | STEFAN et al., "Induction of plasticity in the human motor cortex by paired associative stimulation," Brain, 123, pp. 572-584 (2000) |
| | |
| | |

EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).